

Commissioner for United States Patent and Trademan Alexandria,

Anita Meiklejohn Fish & Richardson 225 Franklin St. Boston MA 02110 In Re: Patent Term Extension

Application for U.S. Patent No. 4,650,787

MAILED

JAN 22 2007

CENTRAL REEXAMINATION UNIT

Dear Ms. Meiklejohn

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year from the previously extended expiration date, i.e., until April 25, 2007. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at ((571) 272-7755 or at mary.till@uspto.gov by e-mail.

Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc:

Office of Regulatory Policy

5600 Fishers Lane (Rockwall II Rm. 1101) Rockville, MD 20857

Attention: Beverly Friedman

RE: vapreotide acetate FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Debiovision Inc. Request for Patent Term Extension U.S. Patent No. 4,650,787

CERTIFICATE OF INTERIM EXTENSION

On March 23, 2006, Debiovision Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for a second subsequent interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the drug product Sanvar®. The application indicates that a New Drug Application for the human drug product Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional year as required by 35 U.S.C. § 156(d)(5)(B). Since it is apparent that the regulatory review period has continued beyond the extended expiration date of the patent (April 25, 2006), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the extended expiration date of the patent, i.e., until April 25, 2007.

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Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office